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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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STITES & HARBISON PLLC  
1199 NORTH FAIRFAX STREET  
SUITE 900  
ALEXANDRIA, VA 22314

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/367,496

Applicant(s)

AGUERA ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,6,7,9,10,15,20-22,30 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4,37 and 38 is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7,9,10,15,20-22,30 and 33-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The amendment filed May 22, 2006, is acknowledged and has been entered. Claims 10, 30, and 36 have been amended. Claims 37 and 38 have been added.
2. Receipt of the translation of FR 97 01961, which has been made of record in accordance with 37 C.F.R. § 1.55, is acknowledged.
3. Claims 1, 3, 4, 6, 7, 9, 10, 15, 20-22, 30, and 33-38 are pending in the application and are currently under prosecution.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Grounds of Objection and Rejection Withdrawn***

5. Unless specifically reiterated below, Applicant's amendment filed May 22, 2006, has obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed November 21, 2005.

#### ***Allowable Subject Matter***

6. The prior art does not teach or fairly suggest an isolated nucleic acid molecule comprising the polynucleotide sequence of SEQ ID NO: 7, which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 8.

#### ***Grounds of Rejection Maintained***

##### ***Claim Rejections - 35 USC § 102***

7. The rejection of claims 1, 9, 10, 20, 21, 30, and 36 under 35 U.S.C. 102(b) as being anticipated by Honnorat et al. (*J. Neurol. Neurosurg. Psych.* 1996; **61**: 270-278) (of record), as evidenced by Honnorat et al. (*Eur. J. Neurosci.* 1999 Dec; **11** (12): 4226-4232), is maintained.

At pages 1-8 of the amendment filed May 22, 2006, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Applicant has argued that it is improper to infer enablement from the teachings of Honnorat et al. (1999). In response, as explained in the preceding Office actions, Honnorat et al. (1999) is cited as evidence that the polypeptide described by the prior art (i.e., Honnorat et al. (1996) is the same as the claimed polypeptide. The propriety of citing such an evidentiary reference has been discussed in preceding Office action mailed April 6, 2005; see, e.g., section 9, particularly at pages 6-8. Furthermore, contrary to Applicant's remark, the evidentiary reference is not cited "to infer enablement", as the prior art teaches the purified polypeptide and therefore provides an enabling disclosure of the claimed invention.

At page 1, for example, of Applicant's remarks, it is noted that Applicant has incorrectly characterizes the prior art as teaching "one or more proteins with an apparent molecular weight of approximately 66 kD" (page 1, paragraph 4). Contrary to Applicant's remarks, the prior art does not teach a plurality of proteins; rather, the prior art teaches a *single* purified polypeptide, which is described as having a molecular weight of 66 kDa. This is apparent, given, for example, the title of the publication: "Antibodies to a subpopulation of glial cells and a **66 kDa developmental protein** in patients with paraneoplastic neurological syndromes" (emphasis added).

Applicant has cited the second paragraph at page 275 of the publication in an attempt to support of their assertion that the prior art teaches a plurality of polypeptides having an approximate molecular weight of 66 kDa. However, the paragraph to which Applicant specifically refers does not describe such a plurality of proteins; and, it is aptly noted that the third paragraph at page 275 describes, not a plurality of proteins, but rather "a principal band of 66 kD apparent weight", which was recognized by all the antisera tested. In fact, throughout the remainder of the publication, the disclosure makes reference to only a *single* protein (i.e., "*the 66 kDa protein* (italicized for emphasis)), never a plurality of proteins.

At page 2, for example, of Applicant's remarks, Applicant states the data presented by the prior art "shows an immunoperoxidase stained Western blot with diffuse bands migrating at a position of what can only be estimated as approximately 66 kDa". Contrary to Applicant's remarks, the prior art does not describe the results of their analysis in a manner that suggests

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such imprecision; moreover, the Examiner objects to Applicant's subjective characterization of the data shown in Figure 7 at page 276. The prior art *unequivocally* describes the polypeptide recognized by the antisera of patients diagnosed with paraneoplastic neurological syndromes (i.e., the anti-CV2 antibodies) as having a molecular weight of 66 kDa; see, e.g., the title of the publication; page 275, paragraph 2; and page 276, paragraph 1.

At page 2, paragraph 2, Applicant has again argued the prior art does not teach the amino acid sequence of the isolated and purified protein. The merit of this argument has been addressed previously; it is again found unpersuasive in view of the cited evidentiary reference, as absent a showing otherwise, the isolated and purified protein described by the prior art is reasonably deemed the same as the claimed polypeptide.

Once again, if it is Applicant's position that the 66 kDa protein, which was isolated by Honnorat et al. (1996), is somehow different from the claimed invention, the burden is upon the Applicant to prove that the claimed polypeptide differs from that taught by the prior art.

At page 2, paragraph 4, Applicant has remarked that the Examiner is using the present specification as a reference; in response, contrary to Applicant's remarks, the stated ground of rejection makes no reference to the specification.

As to the propriety of citing Honnorat et al. (1999) as an evidentiary reference, this issue has been previously discussed in Office action mailed April 6, 2005; see, e.g., section 9, particularly at pages 6-8.

At page 3, Applicant has argued the Examiner must provide a rationale or evidence tending to show inherency. It is submitted that this obligation has already been met in the preceding Office actions.

Nevertheless, it appears no other 66 kDa polypeptides that bind to anti-CV2 antibodies isolated from patients with paraneoplastic neurological syndromes (PNS) have been described to date, but more importantly, because, as previously noted, Applicant has commented that Honnorat et al. (1999), published after the filing date of the application, describes the work of the inventors, and to a large extent shares the content of the application, it would seem that Applicant, better than anyone else, should know whether the protein isolated by Honnorat et al. (1996) is the same as, or different from the claimed polypeptide.

The amino acid sequence of the isolated and purified 66 kDa protein is undeniably an inherent characteristic, just as the amino acid sequence of *any* protein is an inherent characteristic<sup>1</sup>.

Honnorat et al. (1999) makes *specific* reference to the prior art of Honnorat et al. (1996), remarking that the prior publication describes anti-CV2 autoantibodies found in patients with various combinations of PNS and small cell lung cancer, which recognize a 66 kDa protein called POP66; see, e.g., page 4226, column 2. Thus, it is submitted that it should be apparent that the disclosure by Honnorat et al. (1999) represents a further characterization of the same protein, as it includes a description of the amino acid sequence encoded by a cDNA molecule encoding the earlier isolated protein; see, e.g., the abstract; and page 4230, Figure 5. So, while although the prior art does not expressly describe the amino acid sequence of the isolated 66 kDa protein, as evidenced by Honnorat et al. (1999), and absent a showing of any difference, the isolated protein is deemed the same as the claimed polypeptide comprising the amino acid sequence set forth as SEQ ID NO: 8.

Applicant's remarks concerning the specific fact patterns of cited case law, such as *In re Best*, 195 USPQ 430 (CCPA 1977), are noted but considered largely superfluous to the issue at hand, particularly since M.P.E.P. § 2112 states the following:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." *Id.*

See also MPEP §§ 2112.01 and 2141.02.

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<sup>1</sup> See, e.g., Dorland's Illustrated Medical Dictionary, which is available on the Internet and includes a definition of the term "protein" that states "each protein has a unique genetically defined amino acid sequence which determines its specific shape and function" (Copyright © 2006 Merck & Co., Inc.).

At page 6 of the remarks, Applicant has argued the prior art fails to provide an enabling description of the claimed invention. In response, the claims are directed to a purified polypeptide comprising the amino acid sequence of SEQ ID NO: 8. As evidenced by Honnorat et al. (1999), the prior art teaches a purified polypeptide comprising the amino acid sequence of SEQ ID NO: 8. The methodology utilized to purify the protein is described by the prior art (see, e.g., page 270, column 2, through page 272, column 2); thus, contrary to Applicant's assertion, the disclosure by the prior art would enable the artisan to make the claimed invention. Moreover, inasmuch as the methodology described was routine and conventional at the time, it is submitted that no undue and/or unreasonable experimentation would have to be performed to do so.

At page 8, Applicant's remarks again might suggest the prior art teaches a plurality of proteins; however, as explained above, the prior art teaches only a single protein having a molecular weight of 66 kDa, which binds to anti-CV2 antibodies isolated from patients diagnosed with PNS.

Also at page 8, Applicant has asserted, "no antibody preparation was described in Honnorat *et al.* (1996) that could be used to identify a protein" (page 8, paragraph 2). In response, contrary to Applicant's remarks, the prior art describes the antibody preparation that was used to identify the 66 kDa polypeptide, which, as evidence by Honnorat et al. (1999), comprises the amino acid sequence set forth as SEQ ID NO: 8; see, e.g., page 270, column 2.

Accordingly, Applicant's arguments have been carefully considered but not found persuasive.

8. The rejection of claims 30 and 36 under 35 U.S.C. 102(b) as being anticipated by Antoine et al. (*J. Neurol. Sci.* 1993 Jul; **117** (1-2): 215-223) (of record), as evidenced by Honnorat et al. (*Eur. J. Neurosci.* 1999 Dec; **11** (12): 4226-4232), is maintained.

At pages 8-10 of the amendment filed May 22, 2006, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

At page 9, paragraph 3, Applicant has argued that use of the specification in rejections is not permissible; in response, there is no reference to the specification in the rejection; see section 22 at pages 25 and 26 of the Office action mailed November 22, 2004. For further clarification, the claims are rejected herein as being anticipated by Antoine et al., as evidenced by Honnorat et al. (1999), and not in light of any teaching or disclosure set forth in the instant specification.

Beginning at page 9, paragraph 4, Applicant has argued that the prior art does not teach the claimed reagent comprising a *purified* peptide comprising a fragment of the polypeptide comprising the amino acid sequence of SEQ ID NO: 8, which binds to anti-CV2 antibodies and is attached to a solid support.

Notably, the specification does not particularly describe the “solid support” to which the claims are directed, as the term “support” is merely mentioned at page 11, line 29, as *that* to which at least one purified polypeptide, derivative, or biologically active fragment thereof, is optionally attached. As explained in the preceding Office actions, given claim 31 (canceled), for example, the “solid support” to which the claims are directed is reasonably interpreted as a fixed specimen of human brain tissue, and as evidenced by Honnorat et al. (1999), Antoine et al. teaches the claimed invention, since Antoine et al. teaches fixed specimens of brain tissue acquired from humans. As further explained in the preceding Office action, in preparing specimens of human brain, Antoine et al. teaches pieces of post mortem adult brain tissue were fixed in a buffer containing 4% paraformaldehyde and 0.2% picric acid (page 217, column 1). Accordingly, it is understood that such fixation would be sufficient to maintain the existing form and structure of all of the constituent elements of the tissue, including, in particular, the 66 kDa protein, which, as evidenced by Honnorat et al. (1999), is present in such tissue and capable of binding to anti-CV2 antibodies.

As to whether or not the 66 kDa protein, which, as evidenced by Honnorat et al. (1999), is present in such tissue and capable of binding to anti-CV2 antibodies is *purified*, the specification provides no standard for ascertaining the requisite degree of purity of the polypeptide that is attached to the support. In addition, a *purified* polypeptide is produced by the process of “purification”, which is defined, for example, by Dorland's Illustrated Medical Dictionary as meaning, “the separating of foreign or contaminating elements from a substance of interest” (Copyright © 2006 Merck & Co., Inc.), which is indeed the outcome achieved by the



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process described by the prior art. Accordingly, claims are broadly but reasonably interpreted to encompass a reagent comprising a polypeptide attached to a solid support that is be purified (i.e., separated from other elements) to any extent, and therefore it is submitted the claimed reagent is indistinguishable from the reagent described by the prior art.

***Claim Rejections - 35 USC § 103***

9. The rejection of claims 3, 6, 7, 15, 22, and 33-35 under 35 U.S.C. 103(a) as being unpatentable over Honnorat et al. (*J. Neurol. Neurosurg. Psych.* 1996; 61: 270-278) (of record), as evidenced by Honnorat et al. (*Eur. J. Neurosci.* 1999 Dec; 11 (12): 4226-4232), in view of US Patent No. 6,455,267 B1, is maintained.

At pages 10-17 of the amendment filed May 22, 2006, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

At page 10 of the remarks, Applicant has requested the Examiner point out wherein the specification disclosures pertaining to the molecular weight of the polypeptide of SEQ ID NO: 8 are found. In reply, it is believed immaterial where in the specification such disclosures appear, and it is not understood why Applicant has requested the Examiner do so.

At page 11, paragraph 2, Applicant has remarked that the issue is obviousness; the Examiner does not disagree, as the claims are rejected under 35 U.S.C. § 103(a).

At page 11, paragraph 3, Applicant has once again remarked that Honnorat et al. is not prior art. As explained in the preceding Office action, Honnorat et al. is cited, not as prior art, but rather as an evidentiary reference. The propriety of citing such evidentiary references has been addressed in the preceding Office action.

Applicant has further remarked that reliance upon the specification is improper. In response, the stated ground of rejection makes no reference to the specification. Claims 3, 6, 7, 15, 22, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honnorat et al. (1996), as evidenced by Honnorat et al. (1999), in view of U.S. Patent No. 6,455,267 B1.

At page 12, Applicant has again argued that it is not an inherent feature of every brain protein having an approximate molecular weight of 66 kDa to comprise the amino acid sequence

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of SEQ ID NO: 8. This argument has been addressed in the preceding Office action. Applicant has further argued that the “diffuse” band on the gel migrating at an apparent molecular weight of approximately 66 kDa very likely contains several proteins. Did Applicant mean to suggest that band comprises several *different* proteins? If so, as explained above, contrary to Applicant’s remarks, Honnorat et al. (1996) does not teach a plurality of proteins; rather, the reference teaches a *single* purified polypeptide, which is described as having a molecular weight of 66 kDa, and the Examiner again objects to Applicant’s subjective characterization of the data shown therein. There is no factual evidence supporting Applicant’s assertion that the band is “diffuse” or comprised of a plurality of different proteins having an approximate molecular weight of 66 kDa, which bind to anti-CV2 antibodies.

At page 12, paragraph 4, Applicant has remarked that the disclosure by the prior art that the availability of a recombinant protein, currently in development, will be instrumental was a reference to the protein found in rat brain. Without acquiescing to Applicant’s point of view, why should the disclosure not be regarded as providing some teaching, suggestion, or motivation to make the claimed invention? Would a recombinant *human* protein not be as instrumental, if not more so, given the disclosure in the very next paragraph that anti-CV2 antibodies are strongly associated with cancer, predominantly in patients with PNS? It is submitted that the artisan of ordinary skill would have been motivated to make the claimed invention, rather than the rat protein, because the entire thrust of the disclosure is directed toward diagnosing PNS in humans; see, e.g., page 270, column 2, paragraph 2.

Applicant has argued that the Examiner has wrongly concluded that the isolated 66 kDa protein, which is disclosed by the prior art, is the same protein described in the evidentiary reference, namely Honnorat et al. (1999). In response, the Office has properly rejected the claims over the prior art, since, as evidenced by Honnorat et al., the 66 kDa polypeptide disclosed by the prior art is reasonably deemed the same as the claimed polypeptide. Is there a difference between the proteins disclosed by Honnorat et al. (1996) and Honnorat et al. (1999)? Moreover, what factual evidence of record is there that suggests the proteins are not the same? If there are any differences between the protein isolated by Honnorat et al. and the protein described by Honnorat et al., Applicant has the burden of showing those differences.

The Examiner has reasonably concluded that the isolated polypeptide disclosed by the prior art is the same as that which is claimed, since the isolated polypeptide has a molecular mass of 66 kDa, as does the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 8. The prior art teaches the isolated polypeptide binds to anti-CV2 antibodies, as does the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 8. The prior art teaches the isolated polypeptide is present in human brain, as is the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 8. This conclusion is further supported by the disclosures of the evidentiary reference, namely Honnorat et al. (1999). Honnorat et al. (1999) teaches some of the same results presented had already been reported in full detail in other publications, including, in particular, Honnorat et al. (1996); see, e.g., page 9, column 1. It is thus apparent that the studies disclosed by Honnorat et al. (1999) are extensions of those studies disclosed by Honnorat et al. (1996). Again, as noted previously, since Applicant comments that Honnorat et al. (1999), published after the filing date of the application, describes the work of the inventors, and to a large extent shares the content of the application, it would seem that Applicant, better than anyone else, should know whether the protein isolated by Honnorat et al. (1996) is the same as, or different from the claimed polypeptide. So, if it is indeed Applicant's assertion that the protein isolated by Honnorat et al. (1996) is somehow different than that which is described by Honnorat et al. (1999) and moreover different from that which is claimed, then, it suggested again that Applicant remedy this issue by providing a showing of factual evidence that supports that assertion.

Applicant has argued that it not an inherent feature of every brain protein that appears to have a molecular mass of 66 kDa to comprise the amino acid sequence set forth as SEQ ID NO: 8. Of course, it not an inherent feature of every brain protein that appears to have a molecular mass of 66 kDa to comprise the amino acid sequence set forth as SEQ ID NO: 8. Nevertheless, as explained above, because, for example, the isolated 66 kDa polypeptide disclosed by the prior art is expressed by human brain cells and binds to anti-CV2 antibodies, the polypeptide disclosed by the prior art is reasonably deemed the same as that which is claimed. Furthermore, given the fact that the studies disclosed by Honnorat et al. (1999) are extensions of the studies disclosed by the prior art, and moreover that Honnorat et al. (1996) actually include results that were already disclosed by the prior art, it seems unreasonable that Applicant has taken the position that the

isolated polypeptide disclosed by the prior art is somehow different than the protein described by Honnorat et al. (1999) without having provided any factual evidence supporting such a position.

Beginning at page 13, Applicant has again argued that it cannot be deduced from the disclosure of Honnorat et al. (1996) that the isolated protein comprises the amino acid sequence of SEQ ID NO: 8 and furthermore Honnorat et al. (1999) does not make possible the unambiguous identification of the isolated protein as such a protein comprising the amino acid sequence of SEQ ID NO: 8. These arguments have been already addressed herein and in the preceding Office action and have not been found persuasive.

At page 13, paragraph 1, Applicant has again argued that it is not proper to use Honnorat et al. (1999) as an evidentiary reference. These arguments have also been addressed.

At page 14, Applicant has argued the secondary reference does not teach the claimed invention. In response, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Throughout the remainder of the pages of remarks addressing this ground of rejection Applicant has continued to reiterate or restate, in essence, the same arguments. In each instance, Applicant's arguments have been carefully considered but not found persuasive for the reasons already addressed herein or in the preceding Office actions.

### ***Conclusion***

10. Claims 4, 37, and 38 are allowed.

11. Claims 1, 3, 6, 7, 9, 10, 15, 20-22, 30, and 33-36 are not allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

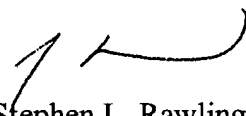
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stephen L. Rawlings, Ph.D.  
Primary Examiner  
Art Unit 1643

slr  
August 2, 2006